

Notice of Allowability

Application No.

10/643,699

Applicant(s)

DRUZGALA ET AL.

Examiner

Shobha Kantamneni

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1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 01/11/2007.
2. ☒ The allowed claim(s) is/are 23-29 and 32-34.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____. |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____ | 7. <input type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

EXAMINER'S STATEMENT OF REASONS FOR ALLOWANCE

The following is an examiner's statement of reasons for allowance:

The present invention is directed to a method for blocking a calcium channel in a patient in need of such blocking comprising administering a calcium channel blocking compound of structure as in claim 23, wherein said compounds are structurally similar to Mibefradil, a well known calcium channel blocker.

The closest prior art reference, US 4,808,605 provides calcium channel blocking data for Mibefradil. The reference lacks the particular compounds as instantly claimed. While Mibefradil a calcium channel blocker demonstrated efficacy in the treatment of hypertension and angina pectoris in man, the drug was eventually withdrawn by the manufacturer due to drug-drug interactions based on inhibition of cytochrome P-450, in particular the CYP3A4-isozyme which is the main metabolizing liver enzyme for mibefradil and a large number of other drugs.

The therapeutic compounds of the instant invention contain an ester group, which does not detract from the ability of these compounds to provide a therapeutic benefit similar to mibefradil, but which makes these compounds more susceptible to degradation by hydrolases, particularly serum and/or cytosolic esterases, and would not have aforementioned disadvantages of mibefradil. Thus, the therapeutic compounds of the instant invention are useful in the method of treating disorders which can be treated by blocking calcium channels comprising the administration of these mibefradil analogs to individuals. Compounds of the present invention can be advantageously used to treat

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individuals suffering from cardiovascular diseases as exemplified by hypertension, angina pectoris, ischemia, arrhythmias and congestive heart failure.

The instant method for blocking a calcium channel in a patient in need of such blocking comprising administering a calcium channel blocking compound of structure as in claim 23 with the therapeutic advantages of mibefradil but which would not have the aforementioned disadvantages of Mibefradil is novel and unobvious over the prior art.

Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shobha Kantamneni whose telephone number is 571-272-2930. The examiner can normally be reached on Monday-Tuesday, Thursday-Friday, 8am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER